

Commercial Success – Appn. No. 09/939,865

# **Exhibit M**

U.S. SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-QSB

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: [ June 30, 2000 ]

Commission file number: 0-28154

SMLX TECHNOLOGIES, INC.

(Exact name of small business issuer as specified in its Charter)

Colorado

84-1337509

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer  
Identification No.)

376 Ansin Boulevard, Hallandale, Florida 33009

(Address of principal executive offices, including zip code)

(954) 455-0110

(Issuer's telephone number)

Indicate by check mark whether the Issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes [ X ] No [ ]

There were 12,104,648 shares of the Registrant's Common Stock outstanding as of August 11, 2000.

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Copy No.: CD19

Offeree Name:

CONFIDENTIAL PRIVATE PLACEMENT MEMORANDUM

800,000 Shares of Common Stock  
Simplex Medical Systems, Inc.  
(A Florida Corporation)

OFFERING PRICE: \$1.00 per Share  
Minimum Purchase 30,000 Shares

Best Efforts Offering - \$500,000 Minimum/\$800,000 Maximum

These Securities Involve a High Degree of Risk  
(See "Risk Factors")

Simplex Medical Systems, Inc., a Florida corporation (the "Company") hereby offers for sale a minimum of 500,000 Shares, maximum 800,000 Shares of its common stock, par value \$.0001 per Share (the "Shares") at a purchase price of \$1.00 per Share. Each Purchaser must purchase a minimum of 30,000 Shares. See, "The Offering". The Shares are offered for sale on a partial, all or none, minimum-maximum basis. All subscriptions received will be deposited into the escrow of Lerner & Pearce, P.A. (the "Escrow Agent") in accordance with the terms of an Escrow Agreement. See, "Escrow Agreement, Exhibit A". If subscriptions for the minimum amount of Shares are not received and accepted by the date May 12, 1996 (the "Expiration Date"), unless extended by the Company for an additional thirty (30) days (the "Extended Expiration Date"), then this Offering will be terminated, and all subscription payments will be returned to the subscribers pursuant to this Offering. See, "Description of Securities".

There is no public market for any securities of Simplex Medical System, Inc. (the "Company") and there is no expectation that a public market will develop. The offering price of the securities has been arbitrarily determined by the Company, and does not necessarily bear any relationship to the Company's assets, net worth, operations or any other generally recognized criteria of value. See "Risk Factors."

This Offering is limited to investors who are "accredited investors" as that term is defined by Rule 501, promulgated under the Securities Act of 1933, as modified by applicable state law, and up to 35 non-accredited investors as qualified by the Company.

The date of this Memorandum is March 28, 1996

## Disclosure's SEC Filings

The following should be read in conjunction with the attached Financial Statements and Notes thereto of the Company.

### RESULTS OF OPERATIONS

#### THREE MONTHS ENDED JUNE 30, 2000 VERSUS THREE MONTHS ENDED JUNE 30, 1999

During the three months ended June 30, 2000, the Company had \$390,106 in revenue compared to \$356,221 in revenue during the corresponding prior year period. The increase was the result of additional revenues from Vector Medical of approximately \$33,000 during 2000.

Expenses for the three months ended June 30, 2000, were approximately the same for the corresponding prior year period.

#### SIX MONTHS ENDED JUNE 30, 2000 VERSUS SIX MONTHS ENDED JUNE 30, 1999

During the six months ended June 30, 2000, the Company had \$962,595 in revenue compared to \$406,372 in revenue during the corresponding prior year period. The increase in revenue was the result of sales of airbrators of \$284,000 (all of which occurred during the quarter ended March 31, 2000) and increased revenues from Vector Medical of approximately \$158,372 during 2000.

Expenses for the six months ended June 30, 2000, were approximately the same for the corresponding prior year period.

### LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2000, the Company had working capital of approximately \$183,945 compared to approximately \$(14,241) at December 31, 1999. The increase is due to the net income for the six months.

As of June 30, 2000, the Company had no material commitments for capital expenditures.

### PART II: OTHER INFORMATION

#### Item 1. Legal Proceedings:

None

#### Item 2. Changes in Securities:

None.

#### Item 3. Defaults Upon Senior Securities:

None

#### Item 4. Submission of Matters to a Vote of Security Holders:

## Disclosure's SEC Filings

SMLX is engaged in the business of developing technological solutions for the medical, dental and other industries and then bringing the technologies to the marketplace.

In October 1999, the Company's quality management system was approved for ISO 9001, BS EN 9001, and ANSI/ASQC Q9001-1994 certification for the design, development and manufacture of dental air abrasion devices. In January 2000, the Company also received EN 46001:1996 certification in this category.

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies dealing with quality system requirements. The mission of ISO is to create a system that, when adhered to, prevents deviations from specific quality requirements at all product stages from design to service.

The Company has also met all of the requirements and has been self-certified to stamp dental air abrasion products shipped into the European Union ("EU") with a "CE" symbol called the "CE Marking", which certifies that the products meet the requirements of all relevant EU directives. Products can no longer be sold in the EU without the "CE" mark.

#### THE COMPANY'S PRODUCTS

Our products can be organized as follows:

1. Medical diagnostic tests - Development completed.
  - (a) Rapid saliva tests (cleared for use in certain foreign countries; not in the U.S.).
2. Medical diagnostic tests - In development.
  - (a) Rapid saliva tests for mumps, measles and rubella.
  - (b) Blood or saliva test for periodontal disease.
3. Drug Delivery Systems - Licensed to Vector Medical Technologies, Inc.
4. Dental products.
  - (a) Airbrator(R) for polishing, cleaning and abrading teeth (cleared for marketing by FDA and for "CE" mark for marketing in EU).
  - (b) Saliva Collector (dental use).
  - (c) Airbrator(R) for use in cavity preparation (510(k) submitted to FDA; cleared for "CE" mark for marketing in EU).
5. Equine products in testing.
  - (a) Bioven - anti-inflammatory drug (submitted to USDA).
  - (b) Equine infectious anemia rapid test.

## Disclosure's SEC Filings

Exclusive Licensing Agreement and Purchase Option Agreement with Vector Medical Technologies, Inc. pursuant to which the Company agreed to transfer to a newly-formed, wholly-owned subsidiary, all of its proprietary technical know-how, patent applications and other assets related to the technologies for the delivery of drugs and other natural and synthetic materials, and to grant to Vector an exclusive ten year license to these assets. In return, Vector agreed to pay to the Company non-refundable advances against future royalties of \$900,000 per year payable monthly in payments of \$75,000. The Company will receive a royalty of 3% to 4% of the net sales derived from the assets transferred, depending on whether or not the assets giving rise to the sales are covered by a patent. Vector may pay the advance royalties for a period of four years subject to the option to purchase the subsidiary. Commencing on April 13, 2000 Vector has the option to purchase the subsidiary and cease paying the advance royalties for a purchase price ranging from \$3.6 million to \$6.6 million depending on the amount of gross sales attributable to the assets in the preceding twelve-month period. As of the date of this Report, the subsidiary has not been formed. The subsidiary to be formed will be devoted to research and development work on the technology transferred to the subsidiary.

C. DENTAL AIRBRATOR(R). The Company has developed and applied for patents and FDA approval on a disposable handpiece which attaches to standard air abrasive etching devices used by dentists for tooth bonding procedures. The product effectively abrades the surface of teeth, but has no effect at all on soft tissue. Because it is disposable and there is no need for extensive sterilization procedures, the product expedites the handling of patients.

During April 1997 the Company received a letter from the FDA stating that the FDA had completed the scientific review portion of the Company's 510(k) premarket notification regarding the Airbrator(R), and the Airbrator(R) was cleared for marketing in the United States for the use of abrading the surface of teeth. Subsequently, in response to the Company's second 510(k) premarket notification regarding the Airbrator(R), the Company was informed verbally that the Airbrator(R) was technically cleared for use in cavity preparation and management expects it to be cleared for marketing once the FDA has inspected the manufacturing site and determined that it complies with the FDA's requirements. The Company's contract manufacturer is currently an FDA registered manufacturing facility.

During July 1997, the Company entered into a Distribution Agreement with Sybron Dental Specialties, Inc. ("Sybron") which appointed Sybron as the exclusive worldwide distributor for the Airbrator(R). Several of the terms of this agreement were amended during December 1997. Sybron paid a \$30,000 one-time license fee to the Company during 1997 for the grant of this distributorship. This agreement was terminated effective December 31, 1998.

D. BIOVEN is an injectable, anti-inflammatory drug which is currently being tested as a treatment for joint inflammation in horses. These tests are being conducted at three sites in Florida. One of the Company's officers developed BIOVEN after fifteen years of extensive research in the field of immunology. BIOVEN is a result of years of experimentation, evaluation and historical study in the field of peptide use. The BIOVEN mode of action is believed to function by reversing the chemical/immunological imbalances that are present in inflammatory processes.

E. FLAVOR ENHANCEMENT. The Company has developed a proprietary process which allows the incorporation of flavor essences into an edible support material using food grade materials and approved printable inks. This process allows a new form of advertising sampler which would let a consumer

## Disclosure's SEC Filings

manufactured by a contract manufacturer for the Company.

Certain sub-assemblies of the Airbrator(R) are manufactured by East Coast Plastics, a contract molding company and these and other components are then filled, assembled and packaged and shipped by East Coast Plastics.

The other products described above will generally be manufactured by the Company.

The Company believes that most components used in the manufacture of its current and proposed products are currently available from numerous suppliers located in the United States, Europe and Asia. However, certain components are available only from a limited number of suppliers. Although the Company believes that it will not encounter difficulties in obtaining these components, there can be no assurance that the Company will be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such components.

The Company anticipates that it will not be required to maintain significant inventory levels of products until the Company's products are deemed acceptable for sale. The Company does not currently have any material backlog. Until the Company is able to market its products on a broad basis, it does not anticipate that its backlog or inventory level will be material. At that time, the Company intends to cause these products to be manufactured for it shortly before they are required for shipment. The Company does not foresee that an extensive period of time will be required from the time of its manufacturing order to the time of final delivery of its products.

### MAJOR CUSTOMERS

During the year ended December 31, 1999, the Company's revenues were primarily derived from two sources. Vector Medical paid the Company \$600,000 under a license agreement, which represented 62% of the Company's revenues, and BioStar paid the Company \$300,000 under a joint venture agreement, representing 31% of the Company's revenues. The Company is dependent on these two sources of revenue.

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### COMPETITION

The markets in which the Company participates are highly competitive. The Company is aware of specialized biotechnology firms, universities and other research institutions which have patented, developed, or are developing technologies and products which are competitive with the Company's products and technologies. These entities, most of which are established, have substantially greater research, marketing and financial resources than the Company. The Company expects that the number of products competing with its saliva-based test products will increase as the potential benefits of saliva-based testing become more widely recognized.

### PATENTS, TRADEMARKS AND PROPRIETARY INFORMATION

The Company owns the rights to U.S. Patent Number 6004191, dated December 21, 1999, which relates to its Airbrator(R) product. The Company has licensed its rights under this Patent to BioStar, S.A. The Company also owns the rights to U.S. Patent Number 5424219 dated June 13, 1995, which relates to the "Method of Performing Assays for Biomolecules and Solid Supports for Use in Such Methods." The Company has licensed its rights under this Patent to Polyfiltrronics, Inc. (See "License Agreement with Polyfiltrronics, Inc." below.)

Company and no patents have been acquired nor are any pending for this product.

D. Blood Group Modifying Substance. Blood group substances are the glycoproteins that surround the surface or coat the surface of the red cells (erythrocytes) and determine the "type" of the blood, i.e. A, AB, O. The Company is currently investigating using its proprietary technology to alter these active substances so as to render the blood "universal donor" type. If successful it will have a major significance in the medical community by allowing for the transfusion of any blood type from a donor to any blood type recipient. The preliminary laboratory studies carried out by the Company have indicated that this universal blood type treatment process is feasible and practical. The market to be targeted initially for this conversion process will be the military for field use as well as to relieve the current shortage in transfusable blood. The Company has no patent nor is one pending for this technology.

E. Solid Phase Matrix Technology and Process. The Company has developed a proprietary method of preparing a support system for diagnostic tests which will increase the sensitivity of the tests and make the manufacture of these tests much more cost effective. This technology will have application in the rapid diagnostic field, the clinical laboratory testing field and in the area of forensic testing. Test systems are currently being adapted to the Simplex Solid Phase Matrix System for the rapid detection of the HIV virus, TB, Hepatitis virus and many tumor marker proteins used in cancer detection. No patent has been acquired nor is any pending for this technology.

F. Dental Air Abrasive Devices. The Company has signed a Joint Development and Marketing Agreement with KIS Technologies, Inc., which gives the Company an equity interest in KIS and a royalty stream on the KIS dental products. See, "Exhibit G". KIS has developed and applied for the patents on a disposable handpiece abrasive dispenser used extensively in the dental field for tooth bonding procedures. Currently, there are no easy to use and disposable products that can accomplish this task for the dentist. The cost savings and the safety of this product to the dentist have made its pre-introduction acceptance positive. The Company will be responsible for production and marketing of this and other KIS Technology, Inc. products worldwide. See, "Business-General", "Certain Transactions" and "Exhibit G".

G. Bioremediation. The problem of "refined" oil marine and environmental pollution is a global crises. The Company has developed and tested a naturally derived strain of bacterial organisms which when placed in an oil polluted area will naturally consume the oil and thus reduce the level of pollution from the oil to accepted levels. This technology is primarily intended for